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10/645,755

08/20/2003

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/645,755 | Applicant(s) MACHOLD ET AL. | |
| | Examiner ROBERT L. NASSER | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's arguments have been found convincing and the current claims have a filing date of 2/28/2000, or the date of the '561 provisional application.

The examiner notes that he had been interpreting the limitation that the rate of heat exchange varies as a function of temperature to mean that as the differential shrank or grew, the rate varied proportionally. However, it appears that this was too limiting of an interpretation and now the claims will be examined with the interpretation that any change in the rate (including from zero to non-zero) satisfies the limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There does not appear to be antecedent basis for the step of setting the temperature of the heat transfer region. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 30, 34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginsburg 5837003. Ginsburg teaches a method of controlling the body temperature including providing a heat transfer catheter 20 having a heat transfer region 62, sensing the body temperature, determining the catheter heat transfer surface temperature (see paragraph at bottom of column 11), selects a target temperature that is different than current body temperature, provides a controller that elevates or depresses the heat transfer region surface temperature by adding or removing heat through a circulating fluid, measuring the difference between body and target temperature, and actuating the controller to adjust the rate of heat addition or removal as a function of the temperature differential (see column 12, line 62 teaching a tapering heat transfer rate based on the temperature differential). Alternatively once the target temperature is reached the method of Ginsburg turns the heating or cooling off. Claim 34 is rejected in that the steps are all performed in a microprocessor. As to claim 37, since there is an initial ramp rate, and the catheter temperature is known, then the system inherently adjusts the rate of heat exchange to achieve the ramp rate.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Applicant's Admission. Beginning on page 4 of the specification, in the paragraph starting at line 27, applicant has admitted that the method for controlling

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the catheter temperature recited in claims 31-33 is a well known control scheme (controlling the fluid temperature to control the catheter surface temperature). Hence, it would have been obvious to modify Ginsburg to use such a control scheme, as it is merely the substitution of one control scheme for another.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg. The exact frequency of performing the steps would have been a mere matter of design choice for one skilled in the art.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Pham et al 6299599. Pham teaches allowing the user to input the target temperature. As such, it would have been obvious to modify Ginsburg to use such a manual input, to allow the system and method to be tuned to the specific needs of the patient at a given time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dae et al 6231594 shows an alternate catheter with a variable heat exchange rate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
September 19, 2010